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EXAMINER	
PAGONAKIS, ANNA	
ART UNIT	PAPER NUMBER
1628	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,683	GLADWIN ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *5-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet, 11/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's payment and submission filed 1, has been received and entered into the present application. Accordingly, prosecution has been reopened.

Applicant's amendment filed 10/13/2009 has been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claims 1-4 and 13-16 are currently under examination and the subject matter of the current Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, has possession of the claimed invention.

Present claim 16 is directed to a method wherein the non-acidified sodium nitrite is administered to the subject in an amount and for a sufficient period of time to reach a circulating concentration in blood of the subject in less than about 25 microM, thereby treating or ameliorating the condition

In particular, the specification and claims as originally fail to provide adequate written description for the newly added claim 16. Applicant has not directed the Examiner as to where in the disclosure the newly added claim is found. Upon review of the instant disclosure, there seems to be no disclosure of claim 16. While it is recognized that adequate written description of a limitation is not required to be stated *in haec verba* in the specification or claims as originally filed, adequate written support for all claim limitations must arise from either an explicit or an implicit suggestion by the disclosure to show that such a concept as now claimed was actually in possession of the Applicant at the time of the invention.

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))...Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys

with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Response to Applicant's Remarks

Applicant alleges that the concentration of circulating blood listed in claim 16 is found implicitly in the disclosure, specifically point to the concentration being 221.82 uM as well as 30 uM and 15 uM. This is not found persuasive. Applicant does not implicitly state "at least about" 15 uM. Firstly, the first concentration amount provided is almost 10 times than that found in instant claim 16. Applicant points to two different blood concentrations of 30 uM and 15 uM in support of "at least about 25 uM", however, Applicant has not pointed to where the "at least about" of the claimed range can be found in the instant specification.

Priority

This application claims benefit of PCT/US2004/22232 filed 7/9/2004 which in turn claims benefit of provisional application 60/485,959 filed 7/9/2003 and 60/511,244 filed 10/14/2003.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, PCT/US2004/22232 filed 7/9/2004 and 60/485,959 filed 7/9/2003 as well as 60/511,244 filed 10/14/2003., fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

All claims are not adequately supported or enabled by the prior-filed applications for a method for treating or ameliorating a condition selected from hepatic or cardiac or brain ischemia-reperfusion injury; pulmonary hypertension or cerebral artery vasospasm in a subject by decreasing blood pressure and/or increasing vasodilation in the subject, the method comprising administering *non-acidified* sodium nitrite to the subject to decrease the blood pressure and/or increase vasodilation in the subject, thereby treating or ameliorating the condition.

It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the previous referred filings does not support the granting of an earlier filing date.. There is no instance, throughout the specification, of any calculation of any ratio. **All claims are given a priority date of October 4, 2006.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant teaches a method comprising the administration of non-acidified sodium nitrate. The specification does not define what encompasses the term "non-acidified" and therefore it is not clear what is being administered. Non-acidified sodium nitrite could infer that the sodium nitrite is in a solution at a neutral or basic pH. Alternatively, non-acidified sodium nitrite could imply inorganic sodium nitrite since it is recognized that inorganic sodium nitrite is a basic molecule having a pH of 9.0 in an aqueous solution. Thus, administration of an aqueous solution of sodium nitrite broadly encompasses non-acidified sodium nitrite. Accordingly, for prior art purposes, non-acidified sodium nitrite will be

interpreted as administration of an inorganic sodium nitrite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. (US 4,650,484).

Shaw et al. disclose methods for treating **ischemic conditions** in a patient having such a condition by administration of a therapeutically effective amount of a vasodilator internally and transdermally to treat the condition (Abstract and claims 1-13). Shaw et al. teach **buccal** administration to get the vasodilator into the systemic circulation which means that it contacts the blood (claim 7). The nitrite, therefore, reacts in the presence of hemoglobin in the subject to release nitric oxide. **Sodium nitrite**, which is not acidified, is specifically named as a vasodilator in a finite list of vasodilators (column 2, lines 35-45). The method is to increase the supply of oxygen to the tissue such as the heart, which would be an ischemic heart (ischemic cardiac tissue and hence a cardiovascular condition) (column 2, lines 51-68). The vasodilator is administered with another agent, which is another vasodilator (claim 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. (US 4,650,484) and Modin et al. (Acta Physiol Scand 2001).

Shaw et al. disclose methods for treating **ischemic conditions** in a patient (which inherently reads on a human) having such a condition by administration of a therapeutically effective amount of a vasodilator internally and transdermally to treat the condition (Abstract and claims 1-13). Shaw et al. teach **buccal** administration to get the vasodilator into the systemic circulation which means that it contacts the blood (claim 7). It is inherent that the nitrite reacts in the presence of hemoglobin in the subject to release nitric oxide. **Sodium nitrite**, which is not acidified, is specifically named as a vasodilator in a finite list of vasodilators (column 2, lines 35-45). The method is to increase the supply of oxygen to the tissue such as the heart, which would be an ischemic heart (ischemic cardiac tissue and hence a cardiovascular condition)(column 2, lines 51-68). The vasodilator is administered with another agent, which is another vasodilator (claim 1).

Shaw et al. is silent on the circulating concentration of 0.6 to 240 microM.

Modin et al. teach that nitric oxide is derived from nitrite (title) and that physiologically relevant concentrations of nitrite evoke vasodilation (page 13, right column Discussion; and page 15, left column last paragraph). Modin et al. teach that the relaxatory effect of nitrite was increased at pH 6.6 over neutral pH (Abstract). Thus Modin et al. teach that **non-acidified nitrite** also has relaxatory effects similar to

"acidified" nitrite (see figures 1, 2, figure 5 and respective discussion in the text). Modin et al. administered various amounts of **sodium nitrite** but noted a threshold response of **10 microM** and near relaxation to basal tone at 1000 microM for the non-acidified sodium nitrite (page 11, Results). Modin et al. teach adding additional agents (ascorbic acid) to enhance the effect of the sodium nitrite (Abstract) Modin et al. conclude that inorganic nitrite evokes vasodilation most likely through nitric oxide release and that this effect is increased if the pH of the environment is reduced to levels normally found in tissues during **ischemia**/hypoxia (page 15, last paragraph).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use sodium nitrite within the range instantly claimed. One of ordinary skill in the art would have been motivated to do this because Shaw et al. teach *a therapeutically effective amount* to the systemic circulation to treat an ischemic condition in a patient and Modin et al. suggest how much sodium nitrite would be beneficial for use in tissues during ischemia. Modin et al. also indicate that human plasma has 0.45 microM nitrite and human serum has 6.6 microM nitrite (page 14, left column) so it is obvious to administer an amount of nitrite that would increase the plasma and serum concentration above the basal level for a therapeutic effect. It is merely routine optimization to obtain a circulating concentration.

It is obvious from the above teachings that Shaw et al. expressly contemplates variation in the dosage amounts and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is

administered as part of a drug combination. Thus, the dosage regimen and/or schedule of administration that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

With regard to claim 16, it is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Response to Applicant's Remarks

Applicant alleges that inorganic nitrites are not equivalent substitutes for recognized nitric oxide donors, such as SNP or SIN these release NO directly, whereas sodium nitrite interacts with chemical reactions with heme group of enzymes and proteins to be metabolized to NO in vivo, per Declaration under 1.132 of Dr. Bruce Freeman. Applicant seems to suggest that different NO donors release NO via different mechanisms of action pathologically, and given this different mechanism one would not be motivated to substitute one donor for another. This is not found persuasive. Per the Declaration under 1.132 of Dr. Bruce Freeman, the mechanisms by which NO is released may vary, nonetheless the desired effect which is the donation of NO does in fact occur (bullet point 3).

Applicant submits that prior to the priority date of the instant application (alleged by Applicant to be October 14, 2003) does not teach non-acidified sodium nitrite as a nitric oxide donor. This is not found persuasive. A careful review has been made of all the priority documents and no instance of "non-acidified sodium nitrite" has been found in any of the priority documents. Additionally, as stated above in the 112 rejection, no mention of "non-acidified sodium nitrite" has been found in the instant specification. It seems that the first recitation of the limitation "non-acidified" is found in the original filing of the

amended claim set. Therefore, in contrast to Applicant's allegations, Applicant's priority date is not drawn to "non-acidified" sodium nitrite. Arguendo the above, Modin et al. teaches that Applicant's non-acidified sodium nitrite are equivalents with acidified sodium nitrite.

Applicant submits the Lundberg declaration which states that the experiments of Modin et al. were performed on isolated aortic rings without circulating blood which are fundamentally different from Applicant's methods and further submits the Kelm declaration stating that Modin is a "poor model for predicting in vivo function because the ex vivo model utilizes excited rat aorta that is maintained at a neutral or acidified pH." Firstly, Applicant's Kelm declaration states that the experiments conducted in model are a "poor model of in vivo function" because the excised aorta was maintained "at a neutral or acidified pH." Applicant is guided to the breadth of their own claim. Applicant's instant limitation claims "non-acidified" which one of ordinary skill in the art would consider sodium nitrite that is not acidic, in other words *neutral* or basic. Modin's use of a neutral pH is therefore "non-acidified." Arguendo the above, Applicant's statement that a neutral pH is a poor model for predicting in vivo function seems to also question the enablement of the instant invention. Applicant's attention is drawn to page 44, lines 24-25 of the instant specification which state "sodium nitrite and sodium nitrate were dissolved in phosphate buffered saline and the pH was adjusted to 7.4" One of ordinary skill in the art would readily recognized that a pH of 7.4 is neutral. Therefore, Applicant's own invention utilizes a neutral pH.

Applicant further alleges that the aortic ring bioassays are not applicable or predictive of what would be observed in an in vivo setting. This is not found persuasive. The art teaches that aortic ring bioassays are in fact predictive of an in vivo effect. Pawloski et al. teaches the use of aortic ring bioassays in order to examine the relationship between NO content and RCE vasoactivity (page 2531, column 2, under Bioassay). The authors conclude that "impaired hypoxic vasodilation by RBCs ex vivo is a physiological correlate of vasocculation in vivo (page 2536, column 1)."

Applicant alleges that acidified inorganic nitrite is preferred and that there is clear teaching in Modin that inorganic nitrite is a more effective vasodilator in an acidic environment. Firstly, as stated above, both the instant example found on page 44 and Modin in fact utilize the same pH. Applicant appears to be of the persuasion that, because Modin teaches both acidic and neutral pH, and specifically the preference of an acidic pH, this somehow constitutes a complete lack of teaching from the use of a non-acidic pH. This is not persuasive. A preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly most limited to that which is preferred and/or exemplified. Thus, the fact that an acidic pH may be preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of, the instantly claimed pH. The fact that the reference may teach embodiments that differ from Applicant's own invention does not negate, or teach away from, the teachings of the reference as a whole and what the reference as a whole would have reasonably suggested to one having ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or

claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 13-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-13 and 20-23 of copending Application No. 10/563,682. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant invention embraces or is embraced by the subject matter of the copending application. One of ordinary skill in the art would recognize the methods in the copending application of treating cerebral ischemia by decreasing blood pressure or increasing vasodilation with a non-acidified sodium nitrite to a subject as embracing the subject matter of instant claims 1-4, 13-15. The same concentrations of sodium nitrite are claimed as well as the subjects and routes of administration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's Remarks

Applicant states that, since none of the copending applications have been allowed, the instant rejections should be withdrawn without the need of a Terminal Disclaimer should they be the only rejections remaining in the present case.

Response to Applicant's Arguments

In the absence of additional remarks to the contrary or any Terminal Disclaimers, and further in light of the fact that these rejections are not the only rejections that remain, the rejections of the present claims over each of the cited copending applications remain proper at this time.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP
/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642